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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,180	08/11/2006	Nicola La Monica	ITR0073YP	3924
210 MERCK P O BOX 2000 RAHWAY, NJ 07065-0907	7590 02/02/2011		EXAMINER SGAGIAS, MAGDALENE K	
			ART UNIT 1632	PAPER NUMBER
			MAIL DATE 02/02/2011	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/589,180	<b>Applicant(s)</b> LA MONICA ET AL.	
	<b>Examiner</b> MAGDALENE SGAGIAS	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,8 and 11-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,8 and 11-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

Applicant's arguments filed 12/08/2010 have been fully considered.

Claims 1, 8, 11-13 are pending and under consideration. Claims 2-7, 9-10 and 14-35 are canceled.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The objection of claim 8 recites the limitation "LT subunit B" in line 2 is withdrawn in view of the canceled claim.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 8, 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "comprises a truncation of amino acids 679-702 of SEQ ID NO: 20". It is not clear if the CEA protein comprises a truncation of one, or 2 or multiple amino acids within the 679-702 of SEQ ID NO: 20. The remaining claims are rejected as being dependent upon a rejected claim.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly

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connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims **1, 8, 11-13** are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claim functional CEA protein variants that comprises a truncation of amino acids 679-702 of SEQ ID NO: 20. The claims read on a broad genus of sequences.

The written description requirement for a genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicants were in possession of the claimed invention. In the instant case, the specification does not sufficiently describe a representative number of functional CEA protein variants that comprises a truncation of amino acids 679-702 of SEQ ID NO: 20 by actual reduction to practice or by disclosure of relevant identifying characteristics.

Applicants claim functional CEA protein variants that comprise a truncation of amino acids 679-702 of SEQ ID NO: 20 by function only, without any disclosed or known correlation between the elements and their function. The specification only provides teachings of CEA variants of the present invention include, but are not limited to sequences that are C- or N-terminally truncated, sequences with conservative substitutions, and sequences with internal deletions or insertions [0083] which can effectively enhance the immune response to the CEA

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protein [0085]. The claims embrace an enormous number of CEA protein variants that comprise a truncation of amino acids 679-702 of SEQ ID NO: 20, constituting a claimed genus. The specification fails to disclose a representative number of the numerous CEA protein variants that comprise a truncation of amino acids 679-702 of SEQ ID NO: 20 of any size or sequence composition that would further be able to effectively enhance the immune response to the CEA protein. The specification does not describe the structure or functional nature of the numerous CEA variant sequences. The specification is further silent on the specific characteristics, or sequence motifs of any CEA variant sequences, that may contribute to effectively enhance the immune response to the CEA protein. The claims thus embrace a claimed genus that encompasses CEA variant sequences yet to be discovered and still have it function. The skilled artisan cannot envision a sufficient number of embodiments of the instant invention from the instant specification because the specification only discloses CEA deletion of amino acids 679--702 of SEQ ID NO: 20.

The state of the art at the time of filing does not provide sufficient information on the subject to overcome the deficiencies of the instant specification. There is no description in the art that allows one to envision a representative number of functional CEA protein variants that comprises a truncation of amino acids 679-702 of SEQ ID NO: 20 by disclosing structural or functional features of CEA protein variants that comprises a truncation of amino acids 679-702 of SEQ ID NO: 20 so that one of skill in the art could envision the claimed invention. Thus the skilled artisan cannot consult the art at the time of filing to envision a sufficient number of embodiments of the instant invention to see that the applicant was in possession of the claimed genus.

Neither the specification of the instant application or the state of the art at the time of filing teaches a structure-function relationship for a representative number of functional CEA

protein variants that comprises a truncation of amino acids 679-702 of SEQ ID NO: 20. As a result, the skilled artisan would not be able to envision the claimed invention. Therefore applicant has not satisfied the written description requirement to show the skilled artisan that they were in possession of the claimed genus.

***Claim Rejections - 35 USC § 103/Necessitated by Amendment***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 1, 13 under 35 U.S.C. 103(a) as being unpatentable over Rice et al (The Journal of Immunology, 167: 1558-1565, 2001(IDS)) in view of Arrington et al (Journal of Virology, 76(9): 4536-4546, 2002 (IDS)) is withdrawn in view of the amendment dated 12/08/2010.

The rejection of claims 1, 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rice et al (The Journal of Immunology, 167: 1558-1565, 2001) in view of Arrington et al (Journal of Virology, 76(9): 4536-4546, 2002) and further in view of Lund et al, (Cancer Gene Therapy, 10: 365-376, 2003 (IDS)) is withdrawn in view of the amendment dated 12/08/2010.

The rejection of claims 1, 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rice et al (The Journal of Immunology, 167: 1558-1565, 2001(IDS)) in view of Arrington et al (Journal of Virology, 76(9): 4536-4546, 2002 (IDS)) and further in view of Klysner, (US 20050063952 A1 (IDS)) is withdrawn in view of the canceled claim 4 in the amendment dated 12/08/2010.

***Allowable Subject Matter***

The objection of claims **11-12** to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims is withdrawn in view of the amendment dated 12/08/2010.

***Conclusion***

**No claim is allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Magdalene K. Sgagias whose telephone number is (571)272-3305. The examiner can normally be reached on Monday through Friday from 9 AM to 5:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paras Peter can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Magdalene K. Sgagias, .  
Art Unit 1632

/Anne-Marie Falk/  
Primary Examiner, Art Unit 1632